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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1656

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/025,222

Applicant(s)

PELLETIER ET AL.

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 66,72,86-88,91 and 105-108 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 88,105 and 106 is/are allowed.  
6) ☒ Claim(s) 66,72,86,87,91,107 and 108 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 03 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Application***

- [1] Claims 66, 72, 86-88, 91, and 105-108 are pending in the application.
- [2] Applicants' amendment to the claims, filed 5/4/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Receipt of a Statement of Substance of Interview, filed 5/4/2005, is acknowledged. Said Statement corresponds to the telephonic interview conducted on 5/3/2005.
- [4] Applicant's arguments filed 5/4/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

### ***Claim Objections***

- [6] Claim 66 is objected to in the recitation of "[a]n isolated or first purified polypeptide" and should be replaced with, for example, "[a]n isolated or purified first polypeptide."
- [7] Claim 91 is objected to as using an inconsistent format in the claim. Parts (a) and (b) of the claim identify their respective amino acid sequence as "a first" or "a second" amino acid sequence. However, part (c) is not identified as "a third" amino acid sequence. It is suggested that applicants amend the claim to use a consistent format.

***Claim Rejections – 35 USC § 112, First Paragraph***

**[8]** Claims 66, 72, 86-87, 91, and 107-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, “when filing an amendment an applicant should show support in the original disclosure for new or amended claims” and “[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description.”

In the response filed 5/4/2005, applicants assert support for claims 66 and 72 can be found at “Figure 10, in which is shown seven polypeptides that comprises SEQ ID NO:6 at their carboxy terminus, each of which were shown to have the ability to bind SEQ ID NO:4” (page 6, top).

After a careful review of the asserted support, applicants’ showing of support is not persuasive. While the examiner can find support for the full length of SEQ ID NO:2 and the *specific* fragments thereof shown in Figure 10A that have the ability to bind SEQ ID NO:4 as indicated in Figure 10B, the recited first polypeptides of claims 66 and 72 are not so limited. Claim 66 encompasses a genus of polypeptides that comprise

amino acids 380-599 at its C-terminus. Claim 72 encompasses a composition comprising a genus of first polypeptides comprising SEQ ID NO:6 at its C-terminus. In this case, the genus of first polypeptides comprises any sequence of amino acids and limits the positioning of amino acids 380 to 599 of SEQ ID NO:2 (claim 66) or the amino acid sequence of SEQ ID NO:6 (claim 72) to the C-terminus of the claimed polypeptide. The examiner can find no support for a polypeptide having any sequence of amino acids and having amino acids 380 to 599 of SEQ ID NO:2 or the amino acid sequence of SEQ ID NO:6 at the C-terminus. Applicants are invited to show support for the claimed limitations.

In the response filed 5/4/2005, applicants assert support for claims 86-87 and 106-107 can be found at "Figure 10; at page 12, lines 7 to 21 (lines 19-21 in particular); at page 13, line 28 to page 14, line 12; and at page 57, line 3 to page 59, line 23" and "[m]ore particularly, polypeptides having a domain with 100% identity with amino acids 561-599 of SEQ ID NO:2 are included among those polypeptides that comprise SEQ ID NO:6" (page 6, bottom). Although there is no showing of support for the limitations of amended claim 91, the examiner has taken the showing of support for claims 86-87 and 106-107 to similarly apply to claim 91.

After a careful review of the asserted support, applicants' showing of support is not persuasive. The examiner can find support for a polypeptide that has 95% identity or 97% similarity to SEQ ID NO:2 (p. 57, lines 3-10). Further, the examiner can find support for a polypeptide comprising an amino acid sequence that has 100% identity to SEQ ID NO:6 (p. 57, lines 14-19). However, the examiner can find no support for a

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polypeptide having the *combination* of both 95% identity or 97% similarity to SEQ ID NO:2 and having 100% identity to amino acids 561-599 of SEQ ID NO:2. Even assuming arguendo the original application provided support for the combined limitations, the examiner can find no support in the original application for the limitation of "wherein amino acids of said first polypeptide corresponding to amino acids 561-599 of SEQ ID NO:2 have 100% identity with amino acids 561-599 of SEQ ID NO:2." One may argue that a polypeptide having an amino acid sequence that has 100% identity to SEQ ID NO:6 is equivalent to a polypeptide having 100% identity with amino acids 561-599 of SEQ ID NO:2 as the two amino acid sequences are identical. However, the combination of limitations has the result of positionally limiting the "amino acids...corresponding to amino acids 561-599 of SEQ ID NO:2 [that] have 100% identity to amino acids 561-599 of SEQ ID NO:2." The examiner can find no disclosure in the specification that so limits the positioning of the amino acid sequence of amino acids 561-599 of SEQ ID NO:2 in a polypeptide. Applicants are invited to show support for the claimed limitations.

**[9]** The scope of enablement rejection of claims 66, 72, and 86-87 under 35 U.S.C. 112, first paragraph, (¶ [7] of the Office action mailed 3/31/2005) is withdrawn in view of the amendment to the claims.

Regarding claims 66 and 72, it is noted that the recited first polypeptide is required to have SEQ ID NO:6 (amino acids 561-599 of SEQ ID NO:2) present at its C-terminus. The specification provides ample evidence that the amino acid sequence of SEQ ID NO:6 confers the ability to bind to SEQ ID NO:4 when present at the C-terminus

of a polypeptide (Figure 10A-B). Thus, one of skill in the art would predict that a polypeptide comprising SEQ ID NO:6 *at its C-terminus* would have the ability to bind SEQ ID NO:4. It is the examiner's position that a skilled artisan can make and use the full scope of the claimed polypeptide of claim 66 and the claimed composition of claim 72 without undue experimentation.

Regarding claims 86-87, the claimed polypeptides are required to have at least 95% identity or 97% similarity to the full-length (amino acids 1-599) of SEQ ID NO:2 *and* have amino acids corresponding to amino acids 561-599 of SEQ ID NO:2 that share 100% identity to amino acids 561-599 of SEQ ID NO:2. The claimed polypeptides are not required to have amino acids 561-599 of SEQ ID NO:2 at their C-termini. However, that the polypeptides are required to have at least 95% identity or 97% similarity to amino acids 1-599 of SEQ ID NO:2, a skilled artisan would expect the fold of the claimed polypeptides to maintain a conformation similar to that of SEQ ID NO:2 such that the "amino acids...corresponding to amino acids 561-599 of SEQ ID NO:2" that "have 100% identity with amino acids 561-599 of SEQ ID NO:2" would be exposed at the surface of the claimed polypeptides, thus enabling their use in the purification of the polypeptide of SEQ ID NO:4.

**[10]** The scope of enablement rejection of claims 91 and 107-108 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (§ [7] of the Office action mailed 3/31/2005) and the reasons stated below.

**RESPONSE TO ARGUMENT:** Applicants argue the claims have been amended to limit the polypeptides to those that bind SEQ ID NO:4 and have the sequence of SEQ

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ID NO:6. Applicants argue the examiner has “indicated that polypeptides with these characteristics are fully enabled by the specification.”

Applicants' argument is not found persuasive. In this case, all polypeptides encompassed by the scope of the claims are required to: 1) bind SEQ ID NO:4 and 2) possess a biological activity as recited in the claims. As noted above, the full scope of claimed polypeptides would appear to have the ability to bind to SEQ ID NO:4. However, as noted in the previous Office action and undisputed by applicants, the biological function of SEQ ID NO:2 is based solely on sequence similarity and there is no evidence of record that SEQ ID NO:2 exhibits any of the recited biological activities. As such, it is highly unpredictable as to whether SEQ ID NO:2 has even a single one of the recited biological activities, particularly in view of the teachings of Brenner and Scott et al. (cited in the Office action mailed 3/31/2005). In this case, it is just as likely that SEQ ID NO:2 is a non-functional mutant polypeptide.

While it is acknowledged that the amendment “would appear” to overcome the scope of enablement rejection, upon further consideration, the examiner takes the position that, at least for claims 91 and 107-108, the specification fails to enable the full scope of claimed polypeptides without undue experimentation.

### ***Conclusion***

**[11]** Status of the claims:

- Claims 66, 72, 86-88, 91, and 105-108 are pending.
- Claims 88 and 105-106 appear to be in a condition for allowance.




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- Claims 66, 72, 86-87, 91, and 107-108 are rejected.
- Claims 66, 72, 86-87, 91, and 107-108 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

  
**DAVID J. STEADMAN, PH.D.**  
**PRIMARY EXAMINER**